American Association of Tissue Banks®

February 6, 2025

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Marks,

The American Association of Tissue Banks (AATB) appreciates the opportunity to provide comment regarding the following four draft guidance documents published by FDA on January 6, 2025:

- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry

AATB is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

These draft guidance documents help to clarify certain aspects of donor eligibility determinations and provide new recommendations for screening potential HCT/P donors for risk factors and conditions, clinical evidence, and physical evidence of HIV, HCV, and HBV infection. The guidance documents also include recommendations for testing potential HCT/P donors for evidence of HIV, HCV, and HBV infection. As a general matter, we applaud the structural changes and overall approach the agency is taking in this new framework. We also applaud FDA

for making changes to bring HIV risk criteria, specifically with regard to men-who-have-sex-with-men (MSM), in line with similar MSM criteria used for blood donors and for tissue donor criteria in other countries.

We are disappointed to note that the HBV guidance document continues to recommend that HBsAg testing be performed for tissue donors. AATB supports calls from the blood community to evaluate discontinuation of this assay, given that tissue establishments already perform anti-HBc and HBV nucleic acid testing on donors.

We also note that additional clarity could be provided in some areas. For example, the HIV draft guidance states that "in accordance with 21 CFR 1271.75(d), you must determine to be ineligible any potential donor who exhibits clinical evidence of HIV. Examples of clinical evidence of HIV may include..." with examples of clinical evidence of HIV (e.g., "unexplained persistent cough or shortness of breath"). There may be some ambiguity related to the risk factors, including whether the presence of only one of these examples is sufficient to reach an ineligibility determination. For example, is an unexplained persistent cough or shortness of breath enough on its own to make a donor ineligible? Or an unexplained persistent cough or shortness of breath combined with another factor, like unexplained persistent diarrhea? Unless clarified in a final guidance document, we interpret these draft guidance documents to mean that the presence of one example from the list of risk factors is not sufficient evidence to determine a donor ineligible and that tissue establishment medical directors retain the authority to make those decisions.

It is an unfortunate byproduct of the timing of the release of these guidance documents that AATB has not been able to collect membership-wide feedback. Our community has been singularly focused on the direct-to-final guidance documents released at the same time addressing Mtb and sepsis. Accordingly, these comments represent our current analysis; as these draft guidance documents are considered by AATB-accredited tissue banks and as we receive their feedback, we may provide additional comments or identify further points requiring clarification.

AATB applauds FDA's work on these guidance documents, and we look forward to working with the agency to implement them once the guidance documents are issued in their final versions.

Regards,

Marc Pearce, MBA
President and CEO
American Association of Tissue Banks